

K212789 Nitrile Examination Gloves (Tested for Use with Chemotherapy Drugs)Dec 1, 2021
91 days to decisionK212789 · Product code: **LZA** · General Hospital
Source: <https://www.510kdatabase.net/k212789/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Polymer Patient Examination Glove (LZA) |
| Date received | Sep 1, 2021 |
| Decision date | Dec 1, 2021 |
| Days to decision | 91 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | 5r Med Instruments (Chengdu) Co., Ltd. |
| Location | Chengdu, CN |
| Contact | Yuzhang Pan |
| 510(k) history | 2 submissions · 2 cleared · 2021-2021 |

REGULATORY CONSULTANT

| | |
|-----------------|---|
| Consulting firm | Shanghai Truthful Information Technology Co., Ltd. |
| Contact | Boyle Wang |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212789/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 25, 2026